IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
Civil Case No. 1:13-cv-194
Judge Spiegel

RALPH DAVID SCOTT
REBECCA APPLEGATE,
CORY WRIGHT, EX. REL., and
others similarly situated and affected,

Frieda Aaron, Katrina Allen, Sherri Lynn Allen (Baldrick) , Sandy & Brad Arnold, Nicole Baker, Jennifer Ballinger, Kimberly Balzar, Randy Brewer, Cindy Bartlett, Patricia Boone, Deena Borchers, Rebecca Breitenstain, James Brown Jr., Andrew Carr, Sherri Cinquina, Chris Clark, Jessica Cochran, Gary L. Coots, Kathryn Curley, William Dabney, Nellie Davis, Damon Deck, Sandra Dennis, Robert Densler, Kristine Dority, Carolyn Dotson, Dawn (Dooley) Dunklin, Kathy Elliot, Alyssa Engle, Jacob Feltner, Karen Feltner, Christine Geralds, Gloria Greene, Jenny Grimm, Erin Gross, Dorothy Hamilton, Barbara Hensley, Jennifer Hickey, Tammy Hughes, Mary Hurt, Amber Johnson (minor) by Laura Johnson, Sarah Juergens, Valerie Kopp, Sheila Pogue-Krabacher, Patricia Legendre, Beth Leisring, Tammy Mann, Tim Marshall, Julie Martin, Derek Mayfield (minor) by Holly Mayfield, Laura Kathleen Kranbuhl-McKee, Mark McMurren, Randall Metcalf, Sarra Mueller(minor) by Steven Mueller, Joetta Nafe, Tonya Neal, Teresa Nichols, Crystal Pierce, Jeff Potts, Todd Ray, Sandra Radeke, Lynn Ray, Samantha Redrow, Kent Reynolds II, Lisa Reynolds, John Richardson, Jason Riley, Jason Romer, Laura Jo Romito, Dorothy Rose, Josh Roy (minor) by Debbie & Jeff Roy, Mike Sand, Joseph Schimmel, Steven Andrew Schultz, Ronald Schuster, Ali Scully, Brenda Shell, Greg Shott, Donna Smallwood, David Smith, David Snider, Samantha Lynn Thomas (minor), by Jim Thomas, Stephanie Herrim-Threm, Daniel Webber, Brandon Webster, Carol Wilson, Kenny Wilson, Robert Wilson, Billy Wolsing, and Brett Wren.

on behalf of the United States of America, and
State of Ohio, and
Commonwealth of Kentucky.
Plaintiffs/Relators

QUI TAM COMPLAINT
FILED UNDER SEAL
JURY TRIAL DEMANDED

v.

ABUBAKAR ATIQ DURRANI, M.D.,
CENTER FOR ADVANCED SPINE TECHNOLOGIES, INC.,
CINCINNATI CHILDREN'S HOSPITAL MEDICAL CENTER,
WEST CHESTER MEDICAL CENTER, LLC.,
UC HEALTH, INC.,
MEDTRONIC SOFAMOR DANEK, INC.,
MEDTRONIC SOFAMOR DANEK, USA, INC.,
MEDTRONIC, INC.
Defendants.

Plaintiffs/Realtors and the others similarly situated, bring this qui tam action in the name of the United States of America, the State of Ohio, the Commonwealth of Kentucky, by and through undersigned counsel Eric C. Deters, and allege as follows.

THIS CLAIM IS TO BE FILED UNDER SEAL AND HAS BEEN SEPARATELY SERVED UPON THE GOVERNMENT AS REQUIRED BY THE FALSE CLAIMS ACT, WITH WAIVER OF SERVICE UPON DEFENDANTS PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 4(d)(4).

SUMMARY INTRODUCTION

This is an action by qui tam Realtors Ralph David Scott, Cory Wright, and Rebecca Applegate, and other patients of the Defendants who were similarly situated and affected, on behalf of the United States, Ohio, and Kentucky, against Defendants Abubakar Atiq Durrani, M.D. ["Durrani"], Center for Advanced Spine Technologies, Inc. ["CAST"], West Chester Hospital, LLC ["West Chester"], Cincinnati Children's Hospital Medical Center ["Children's"], UC Health, Inc. ["UC Health"] Medtronic Sofamar Danek USA, Inc., Medtronic Sofamar Danek Inc., and Medtronic, Inc. ["Medtronic"] to recover penalties and damages arising from false statements, false claims, billing fraud, conspiracy to defraud, unnecessary surgeries, and fraudulent acts and omissions made in support of false Medicaid, false Medicare claims, false federal and state tax deductions and write-offs, and fraudulently induced payments made to the government ["false claims"] which were knowingly caused by the Defendants and submitted to the government to get the false claims paid by the government.

The false claims were paid to Defendants by the government after Defendants performed medically unnecessary, experimental spine surgeries on Realtors using falsely and improperly marketed medical devices, hardware, and drugs.

During these unnecessary spine surgeries Defendants implanted spinal rods, screws and cages ["hardware"] into Realtors and used a drug called Infuse/BMP-2 ["BMP-2"].

BMP-2 is manufactured, marketed, sold and distributed by Defendant Medtronic under the trade name "Infuse". BMP-2 is not approved by the Food and Drug Administration ["FDA"] for use on the cervical and thoracic spine. See FDA Public Health Notification: Life Threatening Complications Associated with Recombinant Bone Morphogenetic Protein (BMP-2) in Cervical Spine Fusion, July 1, 2008). BMP-2 is also not safe or approved for use on children less than twenty-one (21) years of age. (See Medtronic product package warnings, INFUSE/BMP-2).

For use in spinal surgery, Infuse is approved by the FDA for a limited procedure, performed on a limited area of the spine, using specific components. Specifically, Medtronic received FDA approval for its Infuse product only: a. FDA-Approved Procedure: Anterior Lumbar Interbody Fusion ("ALIF"); b. FDA-Approved Area of Spine: L4 to S1; c. FDA-Approved Components: LT-CAGE Lumbar Tapered Fusion Device Component ("LT-CAGE") and the Infuse Bone Graft Component ("BGC"), which includes recombinant bone morphogenetic protein-2 ("rhBMP-2") – a manufactured version of a protein already present in the body meant to promote new bone growth – applied to an absorbable collagen sponge ("ACS") that is designed to disappear over time.

Use of Infuse in lumbar surgery through the back (posterior), or side (lateral), on areas of the spine outside of the L4-S1 region (e.g., the cervical spine), or using components other than or in addition to the LT-CAGE and BCG, is not approved by the FDA, and thus such procedures and/or use of non-FDA approved componentry is termed "off-label."

When used off-label, Infuse frequently causes excessive or uncontrolled (also referred to as "ectopic" or "exuberant") bone growth on or around the spinal cord. When nerves are compressed by such excessive bone growth, a patient can experience, among other adverse events, intractable pain, paralysis, spasms, and cramps in limbs. These side effects also occur even when Infuse is used as approved, typically causing impingement of the sacroiliac nerves resulting in leg stiffness, radiculopathy, burning, numbness, and paralysis .

Notwithstanding overwhelming and substantial evidence (including Medtronic sponsored studies) demonstrating increased risk of adverse reactions from off-label use of Infuse, Medtronic recklessly and/or intentionally misrepresented, minimized, downplayed, disregarded, and/or completely omitted these risks from the general public. In fact, Medtronic promoted the use of the product in off-label manners, thereby demonstrating a conscious disregard for the health and safety of spinal fusion candidates such as the Plaintiff.

Moreover, the actual rate of incidence of serious side effects from off-label use of Infuse is, in fact, much greater than that disclosed by Medtronic and its sponsored studies to physicians and the public. With respect to off-label approaches, such as transforaminal lumbar interbody surgeries ("TLIF"), use of off-label components, and/or use in non-approved spinal sections, Medtronic failed to disclose significant risks of which it knew of or should have known.

Defendant Medtronic improperly marketed and influenced research related to the safety and efficacy of Infuse/BMP-2 both before and after the release of BMP-2 into the marketplace. (*See* United States Senate Committee on Finance, Staff Report on Medtronic's Influence on Infuse Clinical Studies, October 2012, S. Prt. 112-38).

These risks include, but are not limited to, adverse events such as ectopic bone formation, inflammatory reactions, adverse back and leg pain events, radiculitis, retrograde ejaculation, urinary retention, bone resorption, and implant displacement. Medtronic also omitted mention of the risks of sterility and cancer associated with rhBMP-2 use, osteolysis, and worse overall outcomes.

As a result of Defendant's wrongful marketing and wrongful conduct, tens of thousands of patients, including the Realtors, underwent surgeries without knowing the risks associated with off-label use of Infuse. Realtors relied on Defendants false and misleading statements of material fact and those of Medtronic's consultant "opinion leaders" such as Durrani (Medtronic paid physician consultant promoters) to use Infuse in off-label manners. Indeed, absent Medtronic's extensive off-label promotion campaign, physicians, such as the Plaintiff's, would be without the requisite knowledge to perform such off-label Infuse surgeries.

As a result of Defendants off-label Infuse surgery using off-label components, Realtors suffered extreme bodily injuries and damages, including but not limited to: excessive/uncontrolled bone growth, retrograde ejaculation, severe back/leg pain, loss of sensation in the lower extremities, paralysis, inability to sit, laydown, or stand, and lost wages (past,present, and future). As a further result, Realtors required expensive follow up care which was a direct result of the use of hardware and BMP-2, and which claims were paid for by the government.

Defendants knowingly and falsely marketed BMP-2 to Realtors as safe and approved for use in Realtors' cervical and thoracic spine surgeries, then submitted those false claims to the government for payment and/or tax credits and write offs. Defendants knowingly misled all Realtors concerning BMP-2 used in Realtors' spine surgeries. Defendants knowingly misled, created false documents, and purposefully hid BMP-2 used in Realtors' spine surgeries.

Defendants knowingly misled the government concerning the medical necessity, appropriateness, and use of BMP-2 Realtors' cervical and thoracic spine surgeries.

Defendants also knowingly and falsely marketed Medtronic pedicle screw hardware to Realtor Ralph David Scott and Rebecca Applegate as safe and approved for use in Realtor's cervical spine surgeries.

Defendants knowingly and falsely misled the government by stating a) the surgeries on Realtors were medically necessary and b) that the Defendants had obtained proper informed consent to experimentally use hardware and BMP-2 on Realtors, at the expense of the government.

These unnecessary, experimental surgeries and false diagnoses occurred at medical facilities provided by CAST, West Chester, Children's, and UC Health, in the presence of Medtronic sales representatives and with the knowledge, promotion, and encouragement of Medtronic. (See **Exhibit 1**, Operative Report of Ralph David Scott, Medtronic Sales Representative in Surgery Suite when BMP-2/Infuse used "off label" in cervical fusion and without Ralph David Scott's consent; **Exhibit 2**, Operative Report of Rebecca, Medtronic Sales Representative in Surgery Suite when BMP-2/Infuse used "off label" in thoracic fusion and without Rebecca Applegate's consent; **Exhibit 3**, Operative Report of (minor) Cory Wright, Infuse/BMP used "off label" in violation of Medtronic warnings - Notwithstanding its own warnings, BMP/Infuse was supplied by Medtronic to Children's Hospital)

The hardware and BMP-2 was manufactured by Defendant Medtronic, sold by all Defendants, marketed by all Defendants, and distributed by all Defendants. All Defendants improperly profited from the false claims paid by the government as a result of the sale, billing transactions, and off label use of BMP-2 and hardware.

Defendant Durrani holds the patents to several items of hardware and sold the rights to the hardware to Medtronic. See, e.g., US Patent 2010/0249844 A1.

Defendant Durrani is also a paid consultant for Defendant Medtronic. Medtronic paid Durrani consulting fees and other royalties in consideration for using the hardware and BMP-2 in surgeries on Realtors. Furthermore, and Durrani received improper payments and "kickbacks" when he experimentally used the drug BMP-2 and the hardware on Realtors and other unsuspecting patients

In approximately November 2008, Children's terminated Durrani's privileges to practice medicine and perform surgery at their facility.

Upon information and belief, in approximately March 2013, West Chester and UC Health terminated Durrani's privileges to practice medicine and perform surgery at their facility.

In summary, through the joint and several acts and omissions of these Defendants, Realtors became unsuspecting experiments for the real-world testing of Medtronic hardware and BMP-2, by and through Durrani, CAST, West Chester, Children's and UC Health who had secret financial connections to Medtronic, improper financial motives, and submitted false claims. The government paid for these improper and unregulated experiments as a result of false claims made by the Defendants under the veil of "medically necessary" surgeries.

The cumulative cost of the Realtors' surgeries, and the related long term follow up care, physical therapy, prescriptions, injections, and image studies that were falsely submitted to the government for payment is estimated to be approximately $3,500,000.00 - 5,000,000.00. Realtors have reported that there are numerous other similarly situated persons who underwent experimental surgery by these Defendants, and who received Medtronic BMP-2, hardware and screws. The cumulative estimated cost to the government as a result of other false claims made for experimental surgeries using sloppy and techniques, hardware and drugs unapproved by the FDA is hundreds of millions of dollars.

Realtors and their counsel have substantial evidence in their possession that further supports this Complaint. There is so much information that filing herewith was not feasible. Realtors remain ready and willing to share this information with the US Attorney, and will work with the US Attorney to share all information in their possession, custody and control.

PARTIES

1. Realtor Ralph David Scott is a citizen of the Commonwealth of Kentucky.

2. Realtor Rebecca Applegate is a citizen of the State of Ohio.

3. Realtor Cory Wright is a citizen of the State of Ohio.

4. Defendant Abubakar Atiq Durrani ["Durrani"] was born in Pakistan, and frequently travels to Pakistan. Durrani is currently a licensed physician in Kentucky and Ohio, and resides in Ohio.

5. Durrani is currently under investigation by the Food and Drug Administration ["FDA"], Kentucky Board of Medical Licensure, Ohio Board of Medical Licensure, the Ohio Medicaid Fraud Division, the Kentucky Medicaid Fraud Unit, the Office of Inspector General for the US Department of Health and Human Services (Medicare Fraud), and the

Drug Enforcement Agency as a result of reports and complaints made by Realtors and their Counsel.

6. The status of Durrani's citizenship is unknown. His passport submitted to the Kentucky Board of Medical Licensure in 2002 indicates he is a citizen of Pakistan. Upon information and belief, Durrani is a flight risk to avoid prosecution, litigation and restitution.

7. Defendant Durrani can be served at his business location, 6950 Burlington Pike, Florence Kentucky, or in the alternative, 4555 Lake Forest Drive, Suite 150, Cincinnati, Ohio.

8. Defendant Center for Advanced Spine Technologies ["CAST"] is a corporation organized under the laws of Ohio, and has business and medical offices in Kentucky and Ohio. Defendant CAST is owned, in whole or in part, by Defendant Durrani. The agent for service of process for CAST is CT Corporation , 1300 East 9th Street, Suite 1010, Cleveland, Ohio 44114.

9. Defendant West Chester Hospital, LLC is a corporation organized under the laws of Ohio, and provides medical facilities and billing support to physicians, including Durrani, in the State of Ohio. The agent for service of process for West Chester is GH&R Business Services, Inc. 511 Walnut Street, 1900 Fifth Third Center, Cincinnati, Ohio 45202.

10. Defendant Cincinnati Children's Hospital Medical Center ["Children's"] is a corporation organized under the laws of Ohio, and provided medical facilities and billing support to physicians, including Durrani, in the State of Ohio and Kentucky.
11. Children's terminated Durrani's medical, surgery, and admitting privileges in or about December 2008. The agent for service of process for Children's is Frank C Woodside, III, 1900 Chemed Center, 255 E. Fifth Street, Cincinnati, Ohio 45202.

12. Defendant UC Health is a corporation organized under the laws of Ohio, and provides medical facilities, management, administrative, ancillary, and billing support to physicians, including Durrani and West Chester Hospital, in the State of Ohio. The agent for service of process for West Chester is GH&R Business Services, Inc. 511 Walnut Street, 1900 Fifth Third Center, Cincinnati, Ohio 45202.

13. Medtronic Sofamor Danek USA, Inc. is a corporation organized under the laws of the State of Tennessee, with its principal place of business in Memphis, Tennessee, Medtronic has sales representatives, inter alia, in Kentucky and Ohio. Medtronic sales representatives were present during the experimental surgeries performed on Realtors. The agent for service of process for Medtronic is Toni Greer, 2600 Sofamor Danek Dr, Memphis, Tennessee 38132-1719.

14. Medtronic Sofamor Danek Inc. is a corporation organized under the laws of the State of Indiana, with its principal place of business in Memphis, Tennessee, Medtronic has sales representatives, inter alia, in Kentucky and Ohio. Medtronic sales representatives were

present during the experimental surgeries performed on Realtors. The agent for service of process for Medtronic is CT Corporation System, 251 E. Ohio Street Suite 1100, Indianapolis, IN 46204.

15. Defendant Medtronic. Inc. is a Minnesota corporation, with its principal place of business located at 710 Medtronic Parkway, Minneapolis, Minnesota 55432.

16. In this complaint, all Medtronic entities are referenced as "Medtronic".

17. Durrani is a paid consultant for Medtronic. This fact was never disclosed to the Realtors or the government when Durrani experimented on Realtors and submitted false claims.

JURISDICTION & VENUE

18. This action arises under the False Claims Act, 31 U.S.C. §§ 3729 *et seq.* and other applicable state and federal laws.

19. This Court maintains subject matter jurisdiction over this action pursuant 31 U.S.C. § 3732(a) (False Claims Act) and 28 U.S.C. § 1331 (Federal Question).

20. Venue is proper in this Court pursuant to 31 U.S.C. § 3732(a) because: (i) Durrani resides in this district; (ii) Durrani, CAST, West Chester, Children's, UC Health and Medtronic transact business in this district and did so at all times relevant to this complaint; and, as averred below, (iii) Defendants committed acts proscribed by 28 U.S.C. § 3729—acts giving rise to this action—within this district.

21. Before filing this complaint, Realtors served a copy of same upon the United States, together with a written disclosure statement setting forth and enclosing all material evidence and information he possesses, pursuant to the requirements of 31 U.S.C. § 3730(b)(2).

22. Realtors have complied with all other conditions precedent to bringing this action.

23. Ralph David Scott, Cory Wright, and Rebecca Applegate are the original sources of, and have direct and independent knowledge of, all publicly disclosed information on which any allegations herein might be deemed based, and have voluntarily provided such information to the Government before filing this action.

QUI TAM & VIOLATIONS OF THE FALSE CLAIMS ACT

24. Realtors, incorporate adopt and re-allege as if fully restated herein, those allegations contained in the above paragraphs.

25. As described in this Complaint, Defendants by and through their its officers, agents, and employees, violated the False Claims Act, 31 U.S.C. §§ 3729 when they (i) knowingly presented, or caused to be presented, to the United States Government, a false or fraudulent claim for payment or approval; (ii) knowingly made, used, or caused to be

made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government; and (iii) knowingly made, used, or caused to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government.

26. "Knowingly" is defined in the False Claims Act as (1) actual knowledge, (2) deliberate ignorance of the truth or falsity of the information, or (3) reckless disregard of the truth or falsity of the information.

27. As described in this Complaint, and in the alternative, Defendants for the improper benefit of one or all Defendants, by and through their its officers, agents, and employees conspired to commit, and/or committed violation(s) of the False Claims Act, and other improper acts and omissions, as alleged in this Complaint.

28. Defendants alone, or in conjunction with one another, authorized and/or ratified the violations of the False Claims Act committed by their various officers, agents, and employees.

29. Defendants knowingly made false billing claims, falsified medical procedures, made false statements of material fact, falsified medical records, submitted false medical billing records, and/or performed and/or cooperated in medically unnecessary surgeries in order to obtain payment from Medicare and/or obtain other improper consideration and payments from the United States.

30. Defendants preyed on Medicaid and Medicare recipients, including Realtors, because of weaknesses and vulnerabilities of the governments' pre-authorization, payment, reimbursement, and utilization review processes, in contrast to commercial insurers.

31. The type of surgeries at issue herein are substantially expensive, lucrative, spine surgeries.

32. Defendants fraudulently induced the government to pay for Realtors to undergo unnecessary, experimental and/or contraindicated surgeries.

RALPH DAVID SCOTT

33. In approximately May 2010, Ralph David Scott became a covered Medicare beneficiary.

34. On January 25, 2010, Defendant Durrani, acting during the course and scope of his employment with Defendant CAST, performed unnecessary, improper, and/or unsafe experimental surgeries using Medtronic hardware and BMP-2 on Ralph David Scott, with full medical and facility privileges at Defendant facilities UC Health and Westchester Hospital, and thereafter these Defendants knowingly submitted false billing to Medicare in consideration for said surgery.

35. These Defendants improperly received payments and/or other consideration, directly or indirectly, from Medicare after submitting false and deceptive claims for payment, which

claims were based on false information that the surgery on January 25, 2010 was medically necessary; performed properly; with proper warnings, without full disclosure, and without informed consent.

36. Defendants deceptive and false statements concerning the surgery on January 25, 2010 were the basis for Medicare payments to the Defendants.

37. The operative report of Randall Wolf, MD, the thoracic surgeon who performed the first stage of the January 25, 2010 surgery indicates the surgery team was unable to access T9-T10.

38. The report states "the fourth level disk space was not entered, despite even attempts at osteotomy of the calcified lip." Dr. Wolf's report was dictated immediately after the surgery.

39. On January 25, 2010, Dr. Wolf was employed by Defendant CAST. However, Dr. Wolf is no longer employed by Defendant CAST.

40. The Nursing intraoperative note of January 25, 2010 indicates surgery only occurred at levels T6-T9, and not T9-T10.

41. The Intraoperative Nursing implant log of January 25, 2010 indicates the implantation of 8 screws, not 6.

42. The radiology Report of January 25, 2010 indicates posterior fusion T6-T9.

43. However, the operative report of Defendant Durrani indicated he in fact, performed surgery from T9-T10 on January 25, 2010.

44. Defendant Durrani's report of the January 25, 2010 surgery was not dictated until February 2, 2010, and was not signed until March 12, 2010.

45. Defendant Durrani's dictating and record keeping practices have been brought into question at Cincinnati Childrens Hospital, Christ Hospital, West Chester Hospital, and these Defendants as well as other medical facilities.

46. These Defendants also received Medicare payments and/or other consideration for the January 25, 2010 surgery, directly or indirectly, after submitting false, misleading, incorrect claims for payment, including a) that the use of BMP-2 (bone morphogenetic protein) which was proper for this particular surgical application, and that b) Ralph David Scott was warned, informed, and in fact, knowingly consented to the use of BMP-2 on this spinal surgery, which he did not.

47. The January 25, 2010 UC Health billing records for Ralph David Scott indicate the charge for the BMP-2 was additional $13,219.00, with an additional $4,625.00 paid to Dr. Durrani.

48. The total facility and surgical charge of the January 25, 2010 surgery billed to Medicare was $137,705.86.

49. The total physician charge of the January 25, 2010 surgery remains unknown, and further investigation is necessary.

50. The FDA had not approved, and had warned against, the use of BMP-2 for the January 25, 2010 surgery that Defendants performed and received payment and/or other consideration.

51. Defendants knowingly used and were compensated for using BMP-2 on Ralph David Scott without Mr. Scott's knowledge of consent on January 25, 2010.

52. The FDA had previously warned Defendants that BMP-2 should not be used as it was by Defendants David Scott on January 25, 2010.

53. Defendants improperly used and were paid for the use of BMP-2 on Ralph David Scott during the surgery on January 25, 2010. This surgery violated the FDA warning, and was performed without consent, and without warning.

54. Furthermore, September 8, 2010, Defendant Durrani, acting during the course and scope of his employment with Defendant CAST, performed another unnecessary, improper, and/or unsafe surgery on Ralph David Scott at Defendant facilities UC Health and Westchester Hospital.

55. The surgery on September 8, 2010 was an anterior cervical fusion.

56. During the surgery, Defendants implanted cervical pedicle screw hardware into Ralph David Scott's C6-C7 vertebrae.

57. The use of pedicle screws in the cervical spine has not been approved by the FDA except for cases of extreme trauma or end-of-life pain control, neither of which was present here.

58. The use of cervical pedicle screws on Ralph David Scott was an "off label" use.

59. These Defendants received payments and/or other consideration, directly or indirectly, from Medicare after submitting false claims for payment, including facts that the use of BMP-2 and cervical pedicle screw hardware used in this surgery was approved and proper, and that that Ralph David Scott was informed, and in fact, knowingly consented to the use of BMP-2 and cervical pedicel screws on this spinal surgery, which he did not.

60. The September 8, 2010 UC Health billing records for Ralph David Scott have not been produced and are "missing".

61. The total charges of the September 8, 2010 surgery billed to Medicare remain unknown, and further investigation is necessary.

62. The Federal Drug Administration has not approved, and has warned against, the use of BMP-2 and cervical pedicle screws for the September 8, 2010 surgery that Defendants performed and received payment and/or other consideration.

63. The FDA Warning states "*This is to alert you to reports of life-threatening complications associated with recombinant human Bone Morphogenetic Protein (rhBMP) when used in the cervical spine. Note that the safety and effectiveness of rhBMP in the cervical spine have not been demonstrated and these products are not approved by FDA for this use.*"

64. Defendants knowingly used and were compensated for using BMP-2 on Ralph David Scott on September 8, 2010.

65. The FDA had previously warned Defendants that BMP-2 should not be used as it was in the cervical spine by Defendants on September 8, 2010.

66. Defendants improperly used and were paid for the use of BMP-2 on Ralph David Scott during the surgery on September 8, 2010. This surgery violated the FDA warning, and was performed without consent, and without warning.

67. Furthermore, on December 6, 2010, Defendant Durrani, acting during the course and scope of his employment with Defendant CAST, performed unnecessary, improper, and/or unsafe surgery on Ralph David Scott at Defendant facilities UC Health and Westchester Hospital.

68. These Defendants received payments and/or other consideration, directly or indirectly, from Medicare after submitting false claims for payment, including facts that the use of BMP-2 (bone morphogenetic protein) for this surgery was approved and proper, and that that Ralph David Scott was informed, and in fact, knowingly consented to the use of BMP-2 on this spinal surgery, which he did not.

69. The December 6, 2010 UC Health billing records for Ralph David Scott have not been produced and are "missing".

70. The total charges of the December 6, 2010 surgery billed to Medicare remain unknown, and further investigation is necessary.

71. The Federal Drug Administration has not approved, and has warned against, the use of BMP-2 for the December 6, 2010 surgery that Defendants performed and received payment and/or other consideration.

72. Defendants knowingly used and were compensated for using BMP-2 on Ralph David Scott at L4-L5 on December 6, 2010.

73. The FDA had previously warned Defendants that BMP-2 should not be used as it was without patient consent by Defendants on December 6, 2010.

74. Defendants improperly used and were paid for the use of BMP-2 on Ralph David Scott during the surgery on December 6, 2010. This surgery violated the FDA warning, and was performed without consent, and without warning.

75. Furthermore, on September 9, 2011, Defendant Durrani, acting during the course and scope of his employment with Defendant CAST, performed unnecessary, improper, and/or unsafe surgery on Ralph David Scott at Defendant facilities UC Health and Westchester Hospital. These Defendants received payments and/or other consideration, directly or indirectly, from Medicare after submitting false claims for payment, including that use of BMP-2 for this surgery was approved and proper, and that that Ralph David Scott was informed, and in fact, knowingly consented to the use of BMP-2 on this spinal surgery, which he did not.

76. The September 9, 2011 UC Health billing records for Ralph David Scott have not been produced.

77. The total charges of the September 9, 2011 surgery billed to Medicare remain unknown, and further investigation is necessary.

78. The Federal Drug Administration has not approved, and has warned against, the use of BMP-2 for the September 9, 2011 surgery that Defendants performed and received payment and/or other consideration.

79. The surgery on September 9, 2011was a cervical fusion at C1-C2.

80. During the implantation of the cervical pedicel screws, Durrani struck an artery and caused Ralph David Scott to have a stroke (brain bleed).

81. Since the surgery, Ralph David Scott suffers, inter alia, memory loss, extreme headaches, blackouts, paralysis and numbness in his hands, fingers and arms.

82. Defendants knowingly made false claims and were compensated for improperly using BMP-2 and cervical pedicle screws on Ralph David Scott at C1-C2 on September 9, 2011.

83. The FDA had previously warned Defendants that BMP-2 and cervical pedicle screws should not be used as it was by Defendants on September 9, 2011.

84. Defendants improperly used and were paid for the use of BMP-2 and cervical pedicle screw hardware on Ralph David Scott during the surgery on September 9, 2011. This experimental surgery violated multiple FDA warnings and regulations, and was performed without consent, and without warning.

85. Subsequent to the surgery, Ralph David Scott has suffered breathing difficulties, sexual dysfunction, increased pain, swelling, stiffness, slow wound healing, mental status changes, anxiety, and fear.

86. Ralph David Scott complained of these resulting symptoms to Defendants, but Defendants refused, even after the fact, to inform Plaintiff of the use of BMP-2 and risks associated therewith.

87. FDA requires hospitals and other user facilities to report deaths and serious injuries associated with the use of medical devices.

88. Defendants failed to report the improper uses; caused physical injuries; and received improper compensation for using BMP-2; which acts and omissions, alone or in combination, were the proximate cause of the resulting serious injuries and financial damages as alleged in this Complaint.

REBECCA APPLEGATE

89. Rebecca Applegate was admitted to Christ Hospital[1] on June 11, 2008. Surgery was performed on June 11, 2008 and she was discharged on June 12, 2008.

90. Rebecca Applegate's pre-operative diagnosis on operative report stated "degenerative disk disease" but was changed on the discharge summary to "*severe* degenerative disk disease".

91. Durrani's operative report was not dictated until over 9 months after surgery, on March 30, 2009; Durrani's discharge summary was not dictated until 16 months after surgery, on October 17, 2009, and contains a false, changed diagnosis of "severe" degenerative disk disease.

92. Durrani's operative report states he performed fusion on L4-L5 and L5-S1, but he did not.

93. Dr. Desai, a resident assisting Defendants, dictated his operative report on June 11, 2008, and indicates that only L4-L5 fusion was performed, no fusion or device was placed t L5-S1.

94. Progress notes from Dr. Jain (Fellow) dictated June 12, 2006 indicates "S/P L4-L5 TLIF" (status post L4-L5 Translumbar Interbody fusion), no mention of fusion or device at L5-S1.

[1] Christ Hospital is not a party to this action. Upon information and belief, Christ Hospital terminated Durrani's medical, surgical and admitting privileges at the facility after reports of his experimental use of hardware and BMP-2 on patients without informed consent.

95. Durrani used Medtronic Infuse/BMP-2 on Rebecca Applegate on June 11, 2008 without her informed consent.

96. The June 11, 2008 UC Health billing records for Rebecca Applegate have not been produced and are "missing".

97. The total charges of the June 11, 2008 surgery billed to Ohio Medicaid remain unknown, and further investigation is necessary.

98. Defendants knowingly made false claims and were compensated for improperly using BMP-2 on Rebecca Applegate on June 11, 2008.

99. Rebecca Applegate's subsequent treating doctor, Anthony Guanciale, MD indicates that no fusion or interbody device is present at L5-S1.

100. Post operative imaging (MRI) indicates ectopic bone growth, bone graft displacement, and nerve impingement at S1, which has caused permanent nerve damage, leg instability, and paralysis.

101. Durrani's claim that an L5-S1 interbody fusion device was used in this surgery was false (fraud), and this claim was submitted to the government for payment, and was paid.

102. A pre-operative image study (MRI Cervical on Feb. 19, 2009) indicated "No stenosis or herniation is seen at any level" and "minimal posterior disk bulge" at C5-C6.

103. Despite this, Durrani convinced Rebecca Applegate that cervical fusion surgery was medically necessary.

104. Rebecca Applegate was admitted to West Chester Hospital on Oct. 9, 2009; Surgery was performed on Oct. 9, 2009; she was discharged on Oc. 10, 2009.

105. Dr. Durrani pre-operative diagnosis falsely claims "cervical disk herniation at C5-C6" and "spinal stenosis at C5-C6". This is a fraudulent diagnosis. (See 2/19/09 MRI).

106. The operative report was dictated Oct. 28, 2009, 3 weeks after surgery.

107. Defendants used Medtronic Infuse/BMP-2 on Rebecca Applegate on Oct. 9, 2009 without her informed consent, and it was not approved for use in the cervical spine as it was used on Rebecca Applegate on Oct. 9, 2009.

108. The Federal Drug Administration has not approved, and has warned against, the use of BMP-2 and cervical pedicle screws for the Oct. 9, 2009 surgery that Defendants performed and received payment and/or other consideration.

109. Defendants also implanted pedicle screws into Applegate's cervical spine on June 11, 2008, in violation of the FDA regulations which do not permit pedicle screws to be implanted into the cervical spine except for extreme cases of trauma and old age, neither of which were present here.

110. Although Defendant's operative report indicates he implanted "cervical instrumentation" and "interbody cage", these devices are not listed on the West Chester surgical implant log.

111. It is unknown whether Defendants implanted Medtronic hardware into Applegate; it is currently unknown the source of the screws and cage implanted into Rebecca Applegate since these devices were not listed on the surgical implant log.

112. The FDA has two (2) reports of Durrani attempting to illegally import adulterated surgical equipment.

113. The Oct. 9, 2009 UC Health billing records for Rebecca Applegate have not been produced and are "missing".

114. The total charges of the Oct. 9, 2009 surgery billed to Ohio Medicaid remain unknown, and further investigation is necessary.

115. Defendants knowingly made false claims and were compensated for improperly using hardware and BMP-2 on Rebecca Applegate on Oct. 9, 2009.

116. Rebecca Applegate was determined to be disabled in 2010 and now receives Ohio state public assistance and federal Social Security Disability Income benefits.

117. Rebecca Applegate was admitted to West Chester on January 21, 2011; Surgery was performed on Jan. 21, 2011; she was discharged on Jan. 24, 2011.

118. Durrani's operative report was not dictated until three weeks after surgery February 14, 2011.

119. Durrani used Medtronic Infuse/BMP-2 on Rebecca Applegate on Jan. 21, 2011 without her informed consent.

120. Prior to the Jan. 21, 2011 surgery, the FDA had specifically warned physicians that Infuse/BMP-2 was only approved for use in the lumbar spine, and it is was not approved for use in the thoracic spine as it was used on Rebecca Applegate.

121. Durrani also implanted Medtronic rods and screws into Rebecca Applegate's thoracic spine.

122. Two (2) Medtronic Sales Reps were present in the surgery suite on Jan. 21, 2011 when the BMP/Infuse was used "off label", without Applegate's consent, and when the "off label" rods and screw implant experiment took place.

123. Rebecca Applegate's subsequent treating doctor, Anthony Guanciale, MD indicates that thoracic surgery was medically unnecessary.

124. Dr. Durrani's claim that the surgery was medically necessary was a false claim and fraud.

125. The Jan. 21, 2011 UC Health billing records for Rebecca Applegate have not been produced and are "missing".

126. The total charges of the Jan. 21, 2011 surgery billed to Ohio Medicaid remain unknown, and further investigation is necessary.

127. Defendants knowingly used and were compensated for using BMP-2 on Rebecca Applegate on Jan. 21, 2011.

CORY WRIGHT

128. In the fall of 2007, Cory Wright began to have occasional low back pain.

129. Cory, and his parents, James and Julie Wright, sought treatment for Cory at Children's orthopedic clinic and were assigned to Durrani.

130. At all times relevant, Cory Wright was a minor under the age of eighteen (18) years of age, and was a covered beneficiary of his family's health insurance Anthem.

131. Durrani undertook the care and treatment of Cory Wright in approximately September 2007.

132. Durrani ordered two MRI and immediately recommended spinal surgery.

133. Durrani characterized the surgery as "no big deal" and that Cory would be able to wrestle for the high school within four (4) months after the surgery.

134. After only two (2) months of treatment, on November 12, 2007, Dr. Durrani performed a thoracic spinal fusion surgery on Cory Wright at Children's.

135. Durrani performed a surgery that was different from the surgery he had previously explained to the Plaintiffs.

136. The scarring is on Cory Wright's mid back, not his lower back where Dr. Durrani explained it would be.

137. The scarring on Cory Wright caused by Dr. Durrani is extensive, and indicative of sloppy surgical techniques, and a lack of understanding and skill in the use of so called "minimally invasive" spine surgery technique.

138. During the surgery, Dr. Durrani used, and implanted into Cory Wright's body without consent, BMP-2.

139. The FDA has specifically warned physicians not to use BMP-2 in thoracic or cervical spine surgeries as it was used on Cory Wright on November 12, 2007.

140. Durrani and Children's knew of the use of BMP-2 on Cory Wright before the surgery, but did not inform nor warn Plaintiffs of the risks, benefits, and/or potential consequences of the use of BMP-2.BMP-2 was experimentally used on Cory Wright without his permission at Children's by Dr. Durrani.

141. The surgery by Dr. Durrani at Children's was a failure, and Cory now suffers extreme, constant pain.

142. After the surgery, Cory Wright returned to Dr. Durrani at Children's orthopedic clinic and told Dr. Durrnai that he was now suffering extreme, constant pain.

143. Durrani had no answers, was very dismissive, and could not explain the new pain he had caused.

144. The Children's billing records for Cory Wright indicate the total charge for the surgery charge was $93, 202.41, with the Medtronic BMP-2 accounting for an additional $14,560.00, and the Medtronic Infuse Mastergraft Matrix accounting for an additional $3,359.00, and a mystery "miscellaneous charge" of $15,832.00.

145. On September 19, 2008 Cory Wright has an CT Scan at Christ Hospital.

146. The Radiologist at Christ Hospital showed the Plaintiffs that Cory had actually suffered from two pars fractures, but they had long since been healed, and that Cory had probably been born with them.

147. The Christ Hospital Radiologist also showed Plaintiffs that Cory Wright had an extra vertebrae, something that Durrani and Children's had not found.

148. Durrani thereafter ordered a bone scan to rule out a tumor on Cory Wright's spine.

149. After the seven hour test, Dr. Durrani said "I knew it wasn't that. I just wanted to rule it out."

150. Dr. Durrani then ordered Cory Wright back to Christ Hospital for an injection, which did nothing.

151. On December 29, 2008 Cory Wright had another MRI at Children's. After leaving three messages at the Children's orthopedic clinic seeking information about her son, Julie Wright sought treatment elsewhere.

152. At this point, the Wright family had no trust or faith in Durrani or Children's.

153. Cory Wright's subsequent treating and consulting physicians have stated that the surgery by Durrani at Children's was unnecessary, and that the off label, unapproved use of BMP-2 on children, including Cory Wright, was improper.

154. The Medtronic product packaging for Infuse/BMP-2 states it is not to be used on skeletally immature children under the age of 21.

155. Medtronic sales representatives were present in the surgical suite on November 12, 2007 when Children's and Durrani experimentally used BMP-2 on Cory Wright.

156. Cory Wright can no longer tie his own shoes.

157. Cory Wright now suffers constant pain and immobility which he did not have prior to the surgery by Durrani at Children's.

158. Except as otherwise stated herein, all of Cory Wright's pre-operative, surgery, and post-operative treatment by Durrani occurred at Children's.

159. Following the surgery, the Wright's family insurance company, Anthem, rejected the surgical billing from Children's and Durrani.

160. Anthem refused to pay the bill because Children's and Durrani had used BMP-2 on Cory Wright "off label" without the preauthorization and/or approval of Anthem.

161. Thereafter, Children's and Durrani sought collections on the family of Cory Wright for the balance of the bill that Anthem had rejected.

162. Children's and Durrani tried to force the family of Cory Wright to pay for the costs associated with the unapproved use of BMP-2.

163. After fighting with Anthem, Children's and Dr. Durrani for over a year, Children's and Durrani finally agreed to cease collection efforts on the family of Cory Wright.

164. Children's and Durrani improperly and falsely claimed Ohio and Internal Revenue Code tax write offs, low income allotted funds, public funds, and/or other taxpayer, publically financed funds to subsidize and pay for false claims by Durrani, Children's and Medtronic for the surgical experiment on Cory Wright using BMP-2 on November 12, 2007.

165. Children's and Durrani's claim that the surgery was medically necessary was a false claim and fraud.

166. The Nov. 12, 2007 Children's billing records for Cory Wright have not been produced and are "missing".

167. The actual charges of the Nov. 12. 2007 surgery billed to Anthem remain unknown, and further investigation is necessary.

168. Defendants knowingly made false claims and were compensated for improperly using BMP-2 on Cory Wright on Nov. 12 2007.

PRAYER FOR RELIEF

WHEREFORE, that as a direct and proximate result of the false claims, acts and omissions as stated herein, the Realtors, the United States Government, the Commonwealth of Kentucky, the State of Ohio and the public interest have been financially damaged and defrauded as a result of Defendants in violation of the False Claims Act. Realtors demand judgment against Defendants on all claims, request a jury trial on all issues so triable, and the payment of all monetary damages and benefits available and recoverable to Realtors and their counsel under applicable law, and the imposition of fines, penalties and restitution as necessary. Plaintiffs further request:

1. Attorney's fees;
2. Costs associated with the disbursement of this action;
3. Interests;
4. A Hearing prior to settlement or dismissal;
5. A proportionate share of any alternate remedy obtained pursuant to USC Section 3730 (c)(5);
6. All other relief this court deems fitting and proper.

Respectfully submitted,

\s\

Eric C. Deters (38050)
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Cincinnati, Ohio 45203
Phone: (513)-729-1999
Fax: (513) 381-4084
eric@ericdeters.com

JURY DEMAND

Plaintiffs hereby respectfully request trial by jury on all issues.

Respectfully submitted,

Eric C. Deters (38050)

Certificate of Service

The undersigned hereby certifies that the foregoing Complaint has been served upon Hon. Carter M. Stewart, Esq. U.S. Attorney for the Southern District of Ohio, this 21st day of March, 2013 and simultaneously filed UNDER SEAL with the US District Court for the Southern District of Ohio.

Eric C. Deters (38050)

Verification of Ralph David Scott

I hereby verify, swear and certify that the material facts contained in the attached Qui Tam Verified Complaint are true to the best of my knowledge and belief. Further Affiant Sayeth Naught.

Ralph David Scott

Date: 3/20/13

NOTARY SEAL

/s/ The foregoing Verified Complaint was signed in my presence by Ralph David Scott on this the 20th day of March, 2013.

My Commission expires: 3/14/2016

Attached Seal Here:

Notary

Verification of Cory Wright

I hereby verify, swear and certify that the material facts contained in the attached Qui Tam Verified Complaint are true to the best of my knowledge and belief. Further Affiant Sayeth Naught.

Cory Wright
Cory Wright

Date: 3/20/13

NOTARY SEAL

/s/ The foregoing Verified Complaint was signed in my presence by Cory Wright on this the 20th day of March, 2013.

My Commission expires: 3/14/2016

Attached Seal Here:

Charles R. Holbrook
Notary

Verification of Rebecca Applegate

I hereby verify, swear and certify that the material facts contained in the attached Qui Tam Verified Complaint are true to the best of my knowledge and belief. Further Affiant Sayeth Naught.

____

Rebecca Applegate

Date: 3-20-13

NOTARY SEAL

/s/ The foregoing Verified Complaint was signed in my presence by Rebecca Applegate on this the 20th day of March, 2013.

My Commission expires:______________________

Attached Seal Here:

MARK CARTER EPPLEY
ATTORNEY AT LAW
Notary Public, State of Ohio
My Commission Has No Expiration
Section 147.03 R.C.

____

Notary